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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Horst Heirler

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FOLEY AND LARDNER LLP
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3000 K STREET NW
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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,990	Applicant(s) HEIRLER, HORST	
	Examiner LESLIE A. ROYDS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 3-6 and 9-22 are presented for examination.

Applicant's Amendment filed May 26, 2009 has been received and entered into the present application.

Claims 1, 3-6 and 9-22 remain pending and under examination. Claims 11 and 22 are amended.

Applicant's arguments, filed May 26, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 remains rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.2-5 of the previous Office Action dated February 11, 2009, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that para.[0042] at p.13 of the instant specification teachings the melting of the medium-chain triglyceride (MCT) fat and, thus, provides support for the melting of the fat phase, but, nevertheless, the claim has been amended to replace "fat phase" with "medium-chain triglycerides".

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Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's addition of the phrase "medium-chain triglycerides" in place of the phrase "fat phase" has been noted, but does not overcome the clear broadening of subject matter originally disclosed in the specification and claims. In particular, the procedure described at para.[0042] at p.13 specifies that: the medium-chain triglyceride fat is melted *at a temperature not higher than 60°C, adding vegetable oils at the same temperature, and then adding the fish oil concentrate and other fat-soluble ingredients to the liquid mixture immediately before homogenization.* This fails to provide adequate written support for melting the medium-chain triglycerides and adding the refined fish oil concentrate to the fat phase immediately before homogenization with an aqueous phase because: (1) the claim fails to recite the step of melting at a temperature not higher than 60°C, (2) the claim fails to recite the step of adding vegetable oils to the medium-chain triglyceride fat at the same temperature, (3) the claim fails to specify that the fish oil concentrate and the fat-soluble ingredients (understood to be referred to in the instant claim as "the fat phase") are added to the "liquid mixture" immediately before homogenization (i.e., not that the fish oil concentrate is added to the fat phase immediately before homogenization with another aqueous phase as recited in the instant claim). Note also that para.[0042] at p.13 is silent as to the "refined" nature of the fish oil concentrate as now recited in instant claim 22. Accordingly, though Applicant appears to believe that the amendments to instant claim 22 have obviated the lack of written support as described in the previous Office Action, it is noted that, for the reasons described *supra*, the lack of adequate written support has not been remedied and the rejection stands.

For these reasons *supra*, and those previously made of record at p. 2-5 of the Office Action dated February 11, 2009, rejection of claim 22 remains proper.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 9, 14-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT (“Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man”, *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; Abstract Only), cited to show a fact, each already of record, for the reasons of record set forth at p.7-11 of the previous Office Action dated February 11, 2009, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that Alexander fails to teach: (1) a composition comprising 0.5-2% eicosapentaen acid and/or docosahexaen acid as claimed or (2) that the eicosapentaen acid and/or docosahexaen acid are obtained from refined fish oil concentrate. Applicant asserts Brenna fails to disclose a composition that comprises 0.5-2% eicosapentaen acid and/or docosahexaen acid from refined fish oil concentrate and, therefore, does not remedy the deficiencies of Alexander et al. Still further, Applicant opines that the mixture of metabolized products resulting from the conversion of Alexander's composition is totally different from the composition of the instant case (p.9, Remarks).

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant alleges that Alexander et al. fails to teach a composition comprising 0.5-2% eicosapentaen acid and/or docosahexaen acid or that the eicosapentaen acid and/or docosahexaen acid are obtained from refined fish oil concentrate as instantly claimed. This is unpersuasive. Brenna was cited at p.8 of the previous Office Action to clearly show that the essential fatty acid components of the composition disclosed by Alexander et al. would have necessarily produced, e.g., 0.5% docosahexaenoic

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acid due to the fact that essential fatty acids, such as linolenic acid, are converted to docosahexaenoic acid when consumed. See p.8 of the previous Office Action. Therefore, while Alexander et al. may not *expressly* disclose that the composition contains docosahexaenoic and/or eicosapentaenoic acid in the amounts instantly claimed, the citation to Brenna clearly establishes that such an element is necessarily present in the teachings of Alexander et al. Moreover, though it is also noted that Alexander et al. does not explicitly teach that the eicosapentaenoic and/or docosahexaenoic acid are obtained from refined fish oil concentrate, the process by which the eicosapentaenoic and/or docosahexaenoic acid is obtained defines the product by the process from which it was produced (i.e., obtained from refined fish oil concentrate) and, therefore, fails to materially or structurally limit the claimed fatty acids as a whole since the prior art already teaches the obviousness of the instantly claimed product. See MPEP §2113.

Secondly, Applicant's argument that Brenna does not remedy the deficiencies of Alexander because the reference fails to teach a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid is unpersuasive. Applicant is clearly considering the reference individually and not in combination with Alexander et al. as it was applied. Applicant is reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. As a result, focusing solely on the discrete teachings of each of the cited references (i.e., in this case, considering Alexander or Brenna alone without considering them as they were combined together to form the basis of the rejection) is tantamount to examining each of the references inside of a vacuum and fails to be persuasive in establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention *does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a)*. Rather, the test is *what the combined teachings* of the references would have suggested to those of ordinary skill in the art. Please reference *In*

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re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Thirdly, and lastly, Applicant's allegation that the mixture of metabolized products resulting from the conversion of Alexander's composition is totally different from the composition of the instant case is unpersuasive and not a point well taken. Specifically, Applicant opines that Alexander's composition has a fat content of about 42% or 30-44% fat content (Table at p.7 and claim 4 at p.9), from which Applicant then concludes that the average value of LCT content (which is the source of alpha-linolenic acid) is about 34%. It is entirely unclear how Applicant has derived this "average value" of 34% long-chain triglyceride content, since this is not apparently disclosed in Alexander et al. Accordingly, Applicant's attempts to use this allegedly "average value" to assert that the amount of linolenic acid converted to docosahexaenoic acid is outside the scope of the instant claims is similarly unpersuasive.

Alexander et al. explicitly teaches that the amount of LCTs employed in the composition provides 4-10% of the essential fatty acids of linoleic and linolenic acid (p.4, l.10-26). In view of this express teaching that the amount of LCTs used will provide 4-10% of linoleic acid and linolenic acid *in the composition* (i.e., the composition as a whole), it is ultimately irrelevant what Applicant believes the total "fat content" or "long-chain triglyceride content" to be because the 4-10% is disclosed as 4-10% of the composition as a whole, not 4-10% of the total fat content of total LCT content as Applicant asserts. Therefore, since Brenna teaches that 5% of linolenic acid is converted to docosahexaenoic acid, and Alexander et al. teaches that the composition preferably provides 4-10% linolenic acid, then, e.g., an amount of 10% linolenic acid would produce 0.5% docosahexaenoic acid (i.e., $[(10/100) \times (5/100)] = 0.10 \times 0.05 = 0.005 \times 100 = 0.5\%$, which clearly meets the instant claims and clearly contradicts Applicant's allegations that the amount of linolenic acid converted to docosahexaenoic acid is outside the scope of the instant claims.

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For these reasons *supra*, and those previously made of record at p.7-11 of the Office Action dated February 11, 2009, rejection of claims 1, 3, 6, 9, 14-19 and 21 is proper.

Claims 1, 3-6, 9-10 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT (“Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man”, *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; Abstract Only), cited to show a fact, in view of Madigan et al. (“Dietary Unsaturated Fatty Acids in Type 2 Diabetes”, *Diabetes Care*, 23:1472-1477; 2000), Heine et al. (“Linolenic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients”, *Am J Clin Nutr*, 1989 Mar; 49(3):448-456; Abstract Only) and The Merck Index (“Citric Acid”, Monograph 2328, 1989; p.363), each already of record, for the reasons of record set forth at p.11-15 of the previous Office Action dated February 11, 2009, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the additional references of Madigan, Heine and The Merck Index do not remedy the deficiencies of Alexander and Brenna because none of these references teach a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid as instantly claimed.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's argument that the references to Madigan, Heine and The Merck Index do not remedy the deficiencies of Alexander and Brenna because none of these references teach a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid is both unpersuasive and not a point well taken. Applicant is clearly considering each of the references individually and not in combination with the other references (notably, Alexander and Brenna, which, for the reasons provided *supra*, clearly teach a composition comprising 0.5-2% eicosapentaen acid and/or docosahexaen acid) as they were

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applied. Applicant is reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. As a result, focusing solely on the discrete teachings of each of the cited references (i.e., in this case, considering Madigan, Heine or The Merck Index alone without considering they as they were combined with the primary references to Alexander and Brenna to form the basis of the rejection) is tantamount to examining each of the references inside of a vacuum and fails to be persuasive in establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention *does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a)*. Rather, the test is *what the combined teachings* of the references would have suggested to those of ordinary skill in the art. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons *supra*, and those previously made of record at p.11-15 of the Office Action dated February 11, 2009, rejection of claims 1, 3-6, 9-10 and 14-21 is proper.

Claims 1, 3, 6, 9, 11-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; Abstract Only), cited to show a fact, further in view of Bell et al. (WO 97/38593; 1997) and Mendy (U.S. Patent No. 4,407,821; 1983), each already of record, for the reasons of record set forth at p.15-17 of the previous Office Action dated February 11, 2009, of which said reasons are herein incorporated by reference.

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Applicant traverses the instant rejection, stating that the additional references of Bell and Mendy do not remedy the deficiencies of Alexander and Brenna as discussed above because none of the references teach a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid as instantly claimed.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's argument that the references to Bell and Mendy do not remedy the deficiencies of Alexander and Brenna because none of these references teach a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid is both unpersuasive and not a point well taken. Applicant is clearly considering each of the references individually and not in combination with the other references (notably, Alexander and Brenna, which, for the reasons provided *supra*, clearly teach a composition comprising 0.5-2% eicosapentaen acid and/or docosahexaen acid) as they were applied. Applicant is reminded that rejections made under 35 U.S.C. 103(a) are based upon the combination of references. As a result, focusing solely on the discrete teachings of each of the cited references (i.e., in this case, considering Bell and Mendy alone without considering them as they were combined with the primary references to Alexander and Brenna to form the basis of the rejection) is tantamount to examining each of the references inside of a vacuum and fails to be persuasive in establishing non-obviousness because it is the *combined* teachings that are the basis for a proper conclusion of obviousness, not each individual reference alone. In other words, it must be remembered that the references are relied upon in combination and are not meant to be considered separately. To properly conclude obviousness of an invention *does not require the claimed invention to be expressly suggested in its entirety by any one single reference under 35 U.S.C. 103(a)*. Rather, the test is *what the combined teachings* of the references would have suggested to those of ordinary skill in the art. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

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For these reasons *supra*, and those previously made of record at p.15-17 of the Office Action dated February 11, 2009, rejection of claims 1, 3, 6, 9, 11-19 and 21 is proper.

Conclusion

Rejection of claims 1, 3-6 and 9-22 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

September 21, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

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